



PATENT
Attorney Docket No. UM-06632

1651
#111
DB
5/20/03

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Riley S. Rees
Serial No.: 09/640,990
Filed: 08/18/2000
Entitled: **Method Of Manufacture Of A Bioactive Article for Treatment Of Disease**
Group No.: 1651
Examiner: Naff

**INFORMATION DISCLOSURE
STATEMENT TRANSMITTAL**

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RECEIVED
MAY 14 2003
TECH CENTER 1800/2900

CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8(a)(1)(i)(A)

I hereby certify that this correspondence (along with any referred to as being attached or enclosed) is, on the date shown below, being deposited with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Dated: May 9, 2003

By: Mary Ellen Waite

Mary Ellen Waite

Sir or Madam:

Enclosed please find an Information Disclosure Statement and Form PTO-1449, including copies of the references contained thereon, for filing in the U.S. Patent and Trademark Office.

A check for \$180.00 is also enclosed pursuant to 37 C.F.R. § 1.17(p) for filing this Information Disclosure Statement after three months as set forth in 37 C.F.R. § 1.97(c).

The Commissioner is hereby authorized to charge any additional fee or credit overpayment to our Deposit Account No. 08-1290. **An originally executed duplicate of this transmittal is enclosed for this purpose.**

Dated: May 9, 2003

Jason R. Bond

Registration No. 45,439

05/13/2003 HBLANCO 00000014 09640990

01 FC:1806

180.00 GP

MEDLEN & CARROLL, LLP
101 Howard Street, Suite 350
San Francisco, California 94105
617/252-3353



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Riley Rees

Serial No.: 09/640,990

Filed: 8/18/00

Entitled: **METHODS OF MANUFACTURE OF A
BIOACTIVE ARTICLE**

Group No.: 1651

Examiner: Naff

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8(a)(1)(i)(A)

I hereby certify that this correspondence (along with any referred to as being attached or enclosed) is, on the date shown below, being deposited with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA, 22313-1450.

Dated: May 9, 2003

By: 

Mary Ellen Wiate

Examiner Naff:

The citations listed below, copies attached, may be material to the examination of the above-identified application, and are therefore submitted in compliance with the duty of disclosure defined in 37 C.F.R. §§ 1.56 and 1.97. The Examiner is requested to make these citations of official record in this application.

The following printed publications are referred to in the body of the specification:

- U.S. Patent No. 5,972,332

Applicants have become aware of the following printed publications which may be material to the examination of this application:

- U.S. Patent No. 5,512,474
- U.S. Patent No. 5,459,069
- U.S. Patent No. 5,563,068
- U.S. Patent No. 4,576,715

RECEIVED
MAY 14 2003
TECH CENTER 1600/2900

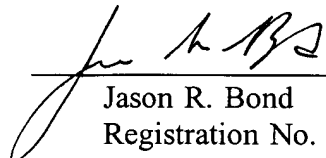
- U.S. Patent No. 5,269,917
- U.S. Patent No. 6,150,104
- U.S. Patent No. 6,210,884
- U.S. Patent No. 4,763,659
- U.S. Patent No. 6,070,103
- U.S. Patent No. 5,836,989
- U.S. Patent No. 5,152,757
- U.S. Patent No. 5,972,332
- Kannon and Garrett, *Dermatol. Surg.*, 21: 583-590 (1995)
- Davies, *Burns*, 10: 94 (1983)
- Myers *et al.* *Am. J. Surgery*, 170: 75-83 (1995)
- Goeddel, *Gene Therapy Expression Technology: Methods in Enzymology* 185, Academic Press, San Diego, CA (1990)
- Boyce *et al.*, *Surgery*, 110: 866-76 (1991)
- Barbul *et al.*, *Surgery*, 105: 764-69 (1989)
- Hansbrough *et al.*, *J. Burn Care Rehabil.*, 14: 485-94 (1993)
- Gilchrest *et al.* *Cell Bio Int. Rep.* 4: 1009 (1980)
- Schafer *et al.* *Exp. Cell. Res.* 183: 112 (1989)
- Cook and Buskirk *In Vitro Cell Dev. Biol.* 31: 132 (1995)
- Hansbrough *et al.*, *J. Am. Med. Assoc.* 262: 2125 (1989)
- Cooper *et al.*, *J. Surg. Res.*, 48: 528 (1990)
- Ronfard *et al.* *Burns*, 17: 181 (1991)
- Tinois *et al.*, *Exp. Cell Res.*, 193: 310 (1991)
- Nanchahal and Ward, *Brit. J. Plas. Surg.* 45: 354 (1992)
- Van der Merve *et al.*, *Burns*, 16: 193 (1990)
- Shi, *Clinical Chemistry*, 47:2, 164-172 [2001]
- Boyce and Ham ["Normal human epidermal keratinocytes," In *In Vitro Models for Cancer Research* (Weber and Sekely, eds.) CRC Press, Boca Raton, FL, pp. 245-274 (1985)
- Schwarz *et al.*, *Wound Repair and Regeneration* 3:204-212 (1995)
- Yao *et al.*, *Hum Gene Ther.* 1999 Feb 10;10(3):419-27

- Yao *et al.*, *Hum Gene Ther.* 1998 Sep 1;9(13):1939-50
- U.S. Patent No. 4,997,443 on 03/5/91 to Walthall *et al*
- U.S. Patent No. 5,294,446 on 03/1994 to Schlameus *et al.*
- U.S. Patent No. 5,487,889 on 1/30/96 to Eckert *et al.*
- U.S. Patent No. 5,529,914 on 04/1996 to Hubbell *et al.*
- U.S. Patent No. 5,545,423 on 08/1996 to Soon-Shiong *et al.*
- U.S. Patent No. 5,643,773 on 07/1/97 to Aebischer *et al.*
- U.S. Patent No. 5,693,332 on 12/2/97 to Hansbrough
- U.S. Patent No. 5,712,163 on 02/27/98 to Parenteau *et al.*
- U.S. Patent No. 5,741,685 on 04/21/98 to Vacanti
- U.S. Patent No. 5,830,507 on 11/1998 to Armstrong
- U.S. Patent No. 5,714,170 on 2/3/98 to Baserga
- WO 88/03785, published on 2/1988
- T.K. Hunt and W.H. Goodson III, "Wound Healing," *Current Surgical Diagnosis & Treatment* (Way; Appleton & Lange), pp. 86-98 (1988)
- Richey *et al.*, "Topical Growth Factors and Wound Contraction in the Rat: Part I. Literature Review and Definition of the Rat Model," *Ann. of Plastic Surgery* 23(2):159-165 (1989)
- G.D. Winter, "Formation of the Scab and the Rate of Epithelization of Superficial Wounds in the Skin of the Young Domestic Pig," *Nature*, 193:293-94 (1962)
- Riley, "Wound Healing," *Am. Fam. Physician*, 24:107-113 (1981)
- Pharmacia Catalog, pp.26-27
- ICN Catalog ,ICN Biomedical Research Products, pp.130-131
- Sigma Catalog, pp. 144-145
- N. Carver *et al.*, "The effect of backing materials on keratinocyte autograft take," *Brit. J. of Plastic Surgery*, 46:228-234 (1993)
- J.F. Woessner, Jr., "Matrix metalloproteinases and their inhibitors in connective tissue remodeling," *FASEB J.*, 5:2145-2154 (1991)
- Green *et al.*, "Growth of Cultured human epidermal cells into multiple epithelia suitable for grafting," *Proc. Nat. Acad. Sci.* 76: 5665-5668 (1979)

- Leigh *et al.*, "Treatment of chronic venous ulcers with sheets of cultured allogenic keratinocytoid," *Brit. J. Derm* 117:591-597 (1987)
- Takashima *et al.*, "Activation of Rabbit Keratinocyte Fibronectin Receptor Function In Vivo During Wound Healing," *J. Invest. Derm.* 86:585-590 (1986)
- Brown *et al.*, "Enhancement of Epidermal Regeneration by Biosynthetic Epidermal Growth Factor," *J. Exp. Med.* 163:1319-1324 (1986)
- Stompro, "Attachment of Growth Factors to Implantable Collagen," *Current Surgery* 47:35-37 (1990)
- Jones *et al.*, "CURRENT RESEARCH REVIEW: Effect of Topical Recombinant TGF- β on Healing of Partial Thickness Injuries," *J. Surg. Res.* 51:344-352 (1991)
- Schultz *et al.*, "EGF and TGF- α in Wound Healing and Repair," *J. Cell. Biochem.* 45:346-352 (1991)
- Ejim *et al.*, "Production of artificial-orientated mats and strands from plasma fibronectin: a morphological study," *Biomaterials* 14(10):743-748 (1993)
- He and McCulley, "Growing human corneal epithelium on collagen sheild and subsequent transfer to denuded cornea *in vitro*," *Curr. Eye Res.* 10(9):851-863 (1991)
- Sasaki *et al.*, *In Vivo* 2000 Jul-Aug;14(4):535-41.
- Nishizaki *et al.*, *Clinical Cancer Research*, 5(5):1015-1023, 1999.
- Lovik *et al.*, *J. Immunol. Meth.*, 179(1):59-69, 1995.

This Information Disclosure Statement under 37 C.F.R. §§ 1.56 and 1.97 is not to be construed as a representation that a search has been made, that additional information material to the examination of this application does not exist, or that any one or more of these citations constitutes prior art.

Dated: May 9, 2003



Jason R. Bond
Registration No. 45,439
MEDLEN & CARROLL, LLP
101 Howard Street, Suite 305
San Francisco, California 94105
608/218-6900

FORM PTO-149
(Modified)

MAY 12 2003

U.S. Department of Commerce
Patent and Trademark Office

Attorney Docket No.: UM-06632

Serial No.: 09/640,990

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use Several Sheets If Necessary)

Applicant: Riley Rees *et al.*

Filing Date: 08/18/00

Group Art Unit: 1651

(37 CFR § 1.98(b))

U.S. PATENT DOCUMENTS

Examiner Initials	Cite No.	Serial / Patent Number	Issue Date	Applicant / Patentee	Class	Subclass	Filing Date
<i>OK</i>	1	5,512,474	04/1996	Clapper <i>et al.</i>	435	182	03/09/94
<i>OK</i>	2	5,459,069	10/17/95	Palsson	435	289.1	1/06/94
<i>OK</i>	3	5,563,068	10/08/96	Zhang <i>et al.</i>	435	295.2	4/21/94
<i>OK</i>	4	4,576,715	3/18/86	Michaels <i>et al.</i>	210	347	2/13/81
<i>OK</i>	5	5,269,917	12/14/93	Stankowski	210	232	2/28/92
	6	6,150,104	11/21/00	Splawski <i>et al.</i>	435	6	8/17/98
	7	6,210,884	4/3/01	Lizardi	435	6	8/11/98
	8	4,763,659	8/16/88	Dunsearth Jr.	128	640	8/20/86
	9	6,070,103	5/30/00	Ogden	607	60	11/5/96
	10	5,836,989	11/17/98	Shelton	607	27	12/26/96
	11	5,152,757	10/6/92	Eriksson	604	305	5/22/91
	13	5,972,332	10/26/99	Rees <i>et al.</i>	424	93.7	04/16/97
	14	4,997,443	03/5/91	Walthall <i>et al.</i>	210	232	12/04/89
	15	5,294,446	03/1994	Schlameus <i>et al.</i>	424	489	01/02/92
	16	5,487,889	1/30/96	Eckert <i>et al.</i>	424	93.1	8/13/93
	17	5,529,914	04/1996	Hubbell <i>et al.</i>	435	182	10/07/92
	18	5,545,423	08/1996	Soon-Shiong <i>et al.</i>	424	484	03/06/95
	19	5,643,773	07/1/97	Aebischer <i>et al.</i>	435	182	04/27/95
	20	5,693,332	12/2/97	Hansbrough	424	426	08/11/95
	21	5,712,163	02/27/98	Parenteau <i>et al.</i>	435	405	03/28/95
	22	5,741,685	04/21/98	Vacanti	435	182	04/21/98
	23	5,714,170	2/3/98	Baserga <i>et al.</i>	424	573	11/16/94
	24	5,830,507	11/1998	Armstrong	424	489	11/18/94

FOREIGN PATENTS OR PUBLISHED FOREIGN PATENT APPLICATIONS

		Document Number	Publication Date	Country / Patent Office	Class	Subclass	Translation	
							Yes	No
	25	WO 88/03785	2/1988	PCT				

OTHER DOCUMENTS (Including Author, Title, Date, Relevant Pages, Place of Publication)

26	Kannon and Garrett, Dermatol. Surg., 21: 583-590 (1995)
27	Davies, Burns, 10: 94 (1983)
28	Myers <i>et al.</i> Am. J. Surgery, 170: 75-83 (1995)
29	Goeddel, Gene Therapy Expression Technology: Methods in Enzymology 185, Academic Press, San Diego, CA (1990)

Examiner:

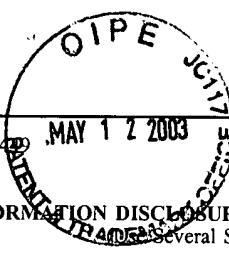
Date Considered:

EXAMINER:

Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

not *considered*
X/c *reference*

RECEIVED
MAY 14 2003
TECH CENTER 1600/2900

FORM PTO-1400
(Modified)U.S. Department of Commerce
Patent and Trademark Office

Attorney Docket No.: UM-06632

Serial No.: 09/640,990

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Include Several Sheets If Necessary)

Applicant: Riley Rees *et al.*

Filing Date: 08/18/00

Group Art Unit: 1651

(37 CFR § 1.98(b))

OTHER DOCUMENTS (Including Author, Title, Date, Relevant Pages, Place of Publication)

- | | |
|----|--|
| 30 | Boyce <i>et al.</i> , <i>Surgery</i> , 110: 866-76 (1991) |
| 31 | Barbul <i>et al.</i> , <i>Surgery</i> , 105: 764-69 (1989) |
| 32 | Hansbrough <i>et al.</i> , <i>J. Burn Care Rehabil.</i> , 14: 485-94 (1993) |
| 33 | Gilchrest <i>et al.</i> , <i>Cell Bio Int. Rep.</i> 4: 1009 (1980) |
| 34 | Schafer <i>et al.</i> [<i>Exp. Cell. Res.</i> 183: 112 (1989) |
| 35 | Cook and Buskirk [<i>In Vitro Cell Dev. Biol.</i> 31: 132 (1995) |
| 36 | Hansbrough <i>et al.</i> , <i>J. Am. Med. Assoc.</i> 262: 2125 (1989) |
| 37 | Cooper <i>et al.</i> , <i>J. Surg. Res.</i> , 48: 528 (1990) |
| 38 | Ronfard <i>et al.</i> , <i>Burns</i> , 17: 181 (1991) |
| 39 | Tinois <i>et al.</i> , <i>Exp. Cell Res.</i> , 193: 310 (1991) |
| 40 | Nanchahal and Ward, <i>Brit. J. Plas. Surg.</i> 45: 354 (1992) |
| 41 | Van der Merve <i>et al.</i> , <i>Burns</i> , 16: 193 (1990) |
| 42 | Shi, <i>Clinical Chemistry</i> , 47:2, 164-172 [2001] |
| 43 | Boyce and Ham ["Normal human epidermal keratinocytes," In <i>In Vitro Models for Cancer Research</i> (Weber and Sekely, eds.) CRC Press, Boca Raton, FL, pp. 245-274 (1985) |
| 44 | Schwarz <i>et al.</i> , <i>Wound Repair and Regeneration</i> 3:204-212 (1995) |
| 45 | Yao <i>et al.</i> , <i>Hum Gene Ther.</i> 1999 Feb 10;10(3):419-27 |
| 46 | Yao <i>et al.</i> , <i>Hum Gene Ther.</i> 1998 Sep 1;9(13):1939-50 |
| 47 | T.K. Hunt and W.H. Goodson III, "Wound Healing," <i>Current Surgical Diagnosis & Treatment</i> (Way; Appleton & Lange), pp. 86-98 (1988) |
| 48 | Richey <i>et al.</i> , "Topical Growth Factors and Wound Contraction in the Rat: Part I. Literature Review and Definition of the Rat Model," <i>Ann. of Plastic Surgery</i> 23(2):159-165 (1989) |
| 49 | G.D. Winter, "Formation of the Scab and the Rate of Epithelization of Superficial Wounds in the Skin of the Young Domestic Pig," <i>Nature</i> , 193:293-94 (1962) |
| 50 | Riley, "Wound Healing," <i>Am. Fam. Physician</i> , 24:107-113 (1981) |
| 51 | Pharmacia Catalog, pp.26-27 |
| 52 | ICN Catalog, ICN Biomedical Research Products, pp.130-131 |
| 53 | Sigma Catalog, pp. 144-145 |
| 54 | N. Carver <i>et al.</i> , "The effect of backing materials on keratinocyte autograft take," <i>Brit. J. of Plastic Surgery</i> , 46:228-234 (1993) |
| 55 | J.F. Woessner, Jr., "Matrix metalloproteinases and their inhibitors in connective tissue remodeling," <i>FASEB J.</i> , 5:2145-2154 (1991) |
| 56 | Green <i>et al.</i> , "Growth of Cultured human epidermal cells into multiple epithelia suitable for grafting," <i>Proc. Nat. Acad. Sci.</i> 76: 5665-5668 (1979) |
| 57 | Leigh <i>et al.</i> , "Treatment of chronic venous ulcers with sheets of cultured allogenic keratinocytes," <i>Brit. J. Derm</i> 117:591-597 (1987) |
| 58 | Takashima <i>et al.</i> , "Activation of Rabbit Keratinocyte Fibronectin Receptor Function In Vivo During Wound Healing," <i>J. Invest. Derm.</i> 86:585-590 (1986) |
| 59 | Brown <i>et al.</i> , "Enhancement of Epidermal Regeneration by Biosynthetic Epidermal Growth Factor," <i>J. Exp. Med.</i> 163:1319-1324 (1986) |
| 60 | Stompro, "Attachment of Growth Factors to Implantable Collagen," <i>Current Surgery</i> 47:35-37 (1990) |

Examiner:

Date Considered:

EXAMINER:

Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

RECEIVED
MAY 14 2003
TECH CENTER 1651/2302

Serial No.: 09/640,990

Applicant: Riley Rees *et al.*

Filing Date: 08/18/00

Group Art Unit: 1651

OTHER DOCUMENTS (Including Author, Title, Date, Relevant Pages, Place of Publication)

[illegible]

Date Considered:

Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

PA
MAY 14 2003
TEST CENTER 1600/2900